08-09-06

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Ensoli	Confirmation No.:	9400
Application No.:	09/555,534	Art Unit:	1648
Filed:	May 31, 2000	Examiner:	Humphrey, Louise Wang Zhiying
For:	HIV TAT, OR DERIVATIVES THEREOF FOR PROPHYLACTIC AND THERAPEUTIC VACCINATION	Attorney Docket No.:	11340-003-999

STATEMENT OF SUBSTANCE OF INTERVIEW UNDER 37 C.F.R. § 1.133

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 1.133 and MPEP 713.04, Applicant submits this Statement of Substance of Interview in connection with the personal interview of July 18, 2006 between Primary Examiner Jeffrey Parkin, Assistant Examiner Louise Humphrey, and Applicant's representatives Adriane Antler, Ann Chen, Giovanni Cozzonne, Paolo Monini, and Shayne Gad in connection with the above-identified application.

During the interview, Applicant's representative Adriane Antler first explained that the invention relates to biologically active Tat protein, fragment and mutants. Ms. Antler explained that while Tat obtained by conventional purification methods easily oxidizes, aggregates, and loses biological activity, the inventor had developed methods to obtain biologically active Tat using, for example, (1) high-pressure liquid chromatography and ion exchange chromatography, or (2) heparin affinity chromatography.

Ms. Antler then proceeded to make the following remarks, consistent with what was set forth in the Amendment Under 37 C.F.R. § 1.114 filed June 14, 2006.

First, Ms. Antler discussed the claim amendments, in particular, the meaning of the terms "biologically active" and "pharmaceutically acceptable for administration to a human." Dr. Gad confirmed Ms. Antler's explanation of the meaning of the term "pharmaceutically acceptable for administration to a human" to require the claimed composition to meet the safety criteria for human administration put forth by regulatory agencies such as the Food and

Drug Administration (FDA) and the European Agency for the Evaluation of Medicinal Products (EMEA), and thus to require the claimed composition not to contain substances which are deemed by such agencies as unacceptable in drugs for human administration.

Second, Ms. Antler explained and Dr. Gad confirmed that a composition comprising either (1) trifluoroacetic acid (TFA) and acetonitrile, or (2) phenylmethylsulfonyl fluoride (PMSF) would not be pharmaceutically acceptable for administration to a human. Examiner Parkin agreed that compositions comprising said substances would not be pharmaceutically acceptable for administration to a human.

Third, Ms. Antler reviewed relevant case law regarding anticipation under 35 U.S.C. § 102.

Fourth, Ms. Antler explained that Chang *et al.* (AIDS. 1997 Oct;11(12):1421-31, "Chang") does not explicitly disclose that the Tat preparation resulting from the first purification method of Chang (as that method is referred to in the Response Under 37 C.F.R. § 1.111 with Amendments, filed December 13, 2005) is pharmaceutically acceptable for administration to a human. Ms. Antler also explained that the first purification method of Chang does not inherently anticipate a Tat preparation that is pharmaceutically acceptable for administration to a human because the resulting Tat preparation may contain TFA and acetonitrile.

Fifth, Ms. Antler explained that Chang does not explicitly disclose that the Tat preparation resulting from the second purification method of Chang (as that method is referred to in the Response Under 37 C.F.R. § 1.111 with Amendments, filed December 13, 2005) is pharmaceutically acceptable for administration to a human. Ms. Antler pointed out that, to the contrary, Chang teaches that the Tat preparation contains PMSF. Ms. Antler also explained that the second purification method of Chang does not inherently anticipate a Tat preparation that is pharmaceutically acceptable for administration to a human because the resulting Tat preparation contains PMSF.

Finally, Ms. Antler explained that none of the other references cited in combination with Chang in support of the 35 U.S.C. § 103 rejection disclose Tat, and also directed the Examiners' attention to case law that stated that an inherent disclosure cannot be used to form the basis of an obviousness rejection.

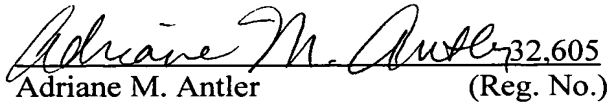
Examiner Parkin indicated that Ms. Antler's arguments regarding Chang's failure to anticipate or make obvious the claimed composition seemed persuasive such that the rejections should be withdrawn, although Examiner Parkin indicated that he wished to take

another look at the purification scheme and the prior art around Applicant's claimed priority date.

Applicant respectfully requests entry of the foregoing remarks into the file history of the above-identified application. It is believed that no fee is due in connection with this Statement; however, in the event any fee is required, please charge the required fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

Date: August 7, 2006



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